

REMARKS

No claims have been amended. No claims have been canceled. No new claims have been added. Claims 1-9 remain pending in the application.

Objections/Rejections Double Patenting

1.0 *The Examiner has rejected claims 1-9 on the grounds of nonstatutory obviousness-type double patenting over claims 1-9 of United States Patent No. 7,199,116.*

A Terminal Disclaimer is attached. Withdrawal of this rejection is respectfully requested.

2.0 *The Examiner has provisionally rejected claims 1-9 on the grounds of nonstatutory obviousness-type double patenting over claims 1-9 of copending Application No. 10/541,781.*

Applicant notes this provisional rejection. An appropriate response will be made once allowable subject matter is identified in the present application and the (781) application.

Objections/Rejections Under 35 U.S.C. §102 and/or 103

3.0 *The Examiner has rejected claims 1-9 under 35 U.S.C. §103(a) as obvious over Partridge et al. (United States Patent No. 5,296,481) in view of Serdula et al. (American Journal of Public Health 1994, Vol. 84, No. 11).*

SUMMARY OF CITED REFERENCES

Partridge et al. discloses controlling weight gain or promoting weight loss by the oral administration of 7-oxo DHEA. Partridge et al. suggests that 7-oxo DHEA is effective for controlling weight gain or promoting weight loss by enhancing the production of thermogenic enzymes which reduce the efficiency of energy metabolism.

Serdula et al. discloses the results of a large population-based telephone survey on weight loss and weight maintenance practices. The survey asked respondents actively involved in efforts to lose or maintain weight whether their efforts involved consumption of fewer calories, fasting, exercising, consumption of appetite suppressant diet pills, consumption of "special products", participation in an organized weight control program, or self-induced vomiting. Serdula et al. does not indicate whether respondents combined consumption of fewer calories with the consumption of "special products".

SUMMARY OF CLAIMED INVENTION

The Present Claimed Invention is directed to a method of achieving accelerated fat loss comprising administration of 7-oxo DHEA, or a pro-drug thereof incapable of in vivo conversion to testosterone, to a dieting mammal.

LEGAL BASIS

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation; either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, NOT in applicant's disclosure. In re VaeckU, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). *See*, M.P.E.P. § 2143.

As to the first criteria, it is necessary to ascertain whether or not the reference motivates one of ordinary skill in the relevant art, having the reference before him, to make the proposed substitution, combination, or modification. In re Linter, 458 F.2d 1013, 173 U.S.P.Q. 560, 562 (CCPA 1972). Obviousness can only be established where there is some teaching, suggestion or motivation in the prior art or in the knowledge generally available to one of ordinary skill in the art, to combine the references and produce the claimed invention. In re Fine, 837 F.2d 1071, 5

U.S.P.Q. 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *See*, M.P.E.P. § 2143.01. "[A]nalysis [of whether the subject matter of a claim is obvious] need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR Int'l v. Teleflex, Inc., 127 S. Ct. 1727, 1740-41, 82 USPQ2d 1385, 1396 (2007) quoting In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336-37 (Fed. Cir. 2006); *see also* DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356, 1361, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006) ("The motivation need not be found in the references sought to be combined, but may be found in any number of sources, including common knowledge, the prior art as a whole, or the nature of the problem itself."); In re Bozek, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969) ("Having established that this knowledge was in the art, the examiner could then properly rely, as put forth by the solicitor, on a conclusion of obviousness 'from common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference.'"); In re Hoeschele, 406 F.2d 1403, 1406-07, 160 USPQ 809, 811-812 (CCPA 1969) (" [I]t is proper to take into account not only specific teachings of the references but also the inferences which one skilled in the art would reasonably be expected to draw therefrom..."). The analysis supporting obviousness, however, should be made explicit and should "identify a reason that would have prompted a person of ordinary skill in the art to combine the elements" in the manner claimed. KSR, 127 S.Ct. at 1731, 81 USPQ2d at 1389.

THE CITED REFERENCES DO NOT DISCLOSE EACH AND
EVERY ELEMENT OF THE CLAIMED INVENTION.

Partridge et al. discloses controlling weight gain or promoting weight loss by the oral administration of 7-oxo DHEA. Partridge et al. indicates that 7-oxo DHEA is effective for controlling weight gain or promoting weight loss by enhancing the production of thermogenic enzymes which reduce the efficiency of energy metabolism (*i.e.*, a given quantity of consumed calories is converted to a smaller quantity of useful or storable energy). The present claimed invention is directed to supporting dieting-induced fat loss by preventing, or at least modulating, the body's innate ability and desire to slow the use of fat stores when the body is subjected to a weight-loss based reduced caloric intake.

Partridge et al. does not teach, suggest, encourage or otherwise induce the consumption of 7-oxo DHEA while dieting to lose weight. Based upon the disclosure in Partridge et al., consumption of 7-oxo DHEA would be expected to promote weight loss without the aggravation associated with dieting. In contrast, the Present Claimed Invention merely supports dieting-induced weight loss.

Serdula et al. does NOT support the Examiner's position as the reference simply discloses the various methods "in vogue" as of 1989 for losing or maintaining weight. Serdula et al. does NOT disclose, teach or suggest that persons responding to the survey were both consuming fewer calories and consuming a "special product", much less the specific dietary supplement 7-oxo DHEA used in the present claimed invention, in an effort to lose weight. Furthermore, the disclosure of Serdula et al. provides little guidance because it lumps so many different products into the category of a "special product". Serdula et al. provides no indication as to the property, characteristic, function or feature of a product that qualifies the product as a "special product". A wide-variety of vastly different weight-loss or weight-maintenance products are available ranging from meal-replacement products, to products promoted for an ability to absorb and remove fat from the body, to products promoted for an ability to increase metabolism, to products promoted for an ability to enhance or suppress the production or activity of a hormone thought to be involved in the body's creation or utilization of fat stores. *See, for example*, MayoClinic.com, Weight-loss pills: What can diet aids do for you? @ mayoclinic.com/print/weight-loss/HQ01160/METHOD=print;

Free Dieting the Weight Loss Guide, Weight Loss Supplements and Diet Pills @ freedieting.com/diet_pill_herbal.htm; and Fat Loss Revealed The Truth About Fat Loss – Everything You Need to Know @ aboutsupplements.com. By painting with such a broad brush, the disclosure of Serdula et al. provides no teaching or guidance relevant to patentability of the present invention.

Withdrawal of this rejection is requested.

4.0 *The Examiner has rejected claims 1-9 under 35 USC §102(b) as anticipated by Kalman et al. (Current Therapeutic Research, Vol. 61, No. 7).*

SUMMARY OF CITED REFERENCES

Kalman et al. reports accelerated weight loss by the consumption of 7-oxo DHEA in combination with a caloric intake of ~1,800 kcal/day.

SUMMARY OF CLAIMED INVENTION

The Present Claimed Invention is directed to a method of achieving accelerated fat loss comprising administration of 7-oxo DHEA, or a pro-drug thereof incapable of in vivo conversion to testosterone, to a mammal eating and drinking sparingly in an effort to lose weight.

LEGAL BASIS

An anticipation rejection under 35 U.S.C. § 102 requires that the cited reference(s) disclose each and every element of the claimed invention. See, Hybritech Inc. v. Monoclonal Antibodies, Inc., 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986); Kloster Speedsteel AB et al. v. Crucible Inc. et al., 230 U.S.P.Q. 81, 84 (Fed.Cir. 1986). A reference anticipates a claim only when the reference discloses each and every element recited in the claim. See, Verdegaal Bros. v. Union Oil Co. of California, 2 U.S.P.Q.2d 1051 (Fed. Cir. 1987) and M.P.E.P. §2131. Accordingly, the “exclusion of a claimed element from a prior art reference is enough to negate anticipation by

that reference.” Atlas Powder Co. v. E.I. duPont De Nemours & Co., 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984).

KALMAN ET AL. DOES NOT DISCLOSE EACH AND
EVERY ELEMENT OF THE CLAIMED INVENTION.

The test group studied in Kalman et al. was predominantly female (28 women and 2 men) with a mean age of 44.5 years. No information is given in Kalman et al. as to the height of the participants. The various “rules of thumb”, general techniques and calculations commonly employed in the weight control industry indicates that a caloric intake of ~1,800 kcal/day for an overweight (*e.g.*, 150 lb) approximately 44 year old women of average height (*i.e.*, 5 ft, 6 inches) is a caloric diet designed for weight maintenance, NOT weight loss. See, for example, Dr. Branch Easy Weight Loss Website @ drbranch.com/index_files/Page658.html (1,395 kcal/day for weight maintenance and 800 kcal/day for healthy weight loss), Columbia University’s Health Q&A Internet Service @ goaskalice-cms.org/scripts/printerfriendly.cfm?questionid=576 (1,600 to 2,400 kcal/day for weight maintenance), Online BMI Calculator:Harris Benedict Equation @ bmi-calculator.net/bmr-calculator/harris-benedict-equation (1,693 kcal/day for weight maintenance assuming a sedentary lifestyle). The weight-maintenance nature of the ~1,800 kcal/day restricted caloric diet set forth in Kalman et al. is further supported by the fact that study participants in the control group - whose diet was restricted to a caloric intake of ~1,800 kcal/day but without the consumption of 7-oxo DHEA - lost virtually no weight during the study period, despite the fact that they had started exercising on a regular basis.

The Present Claimed Invention is directed to the administration of 7-oxo DHEA in combination with a reduced caloric intake with the reduction in caloric intake set to achieve weight loss, while Kalman et al. teaches the administration of 7-oxo DHEA in combination with a restricted caloric intake with the restricted caloric intake set to provide weight maintenance. Since the body reacts differently to a reduction in caloric intake set to achieve weight loss relative to a restricted caloric intake set to provide weight maintenance (*i.e.*, the body tends to decrease its metabolic rate when subjected to a reduced caloric intake designed to achieve weight loss, but would be expected to maintain its normal metabolic rate when subjected to a restricted caloric intake designed to provide weight maintenance) Kalman’s disclosure of the administration of 7-oxo

DHEA in combination with weight maintenance caloric intake does not disclose, teach or suggest to those of ordinary skill in the art to administer 7-oxo DHEA in combination with a weight loss caloric intake.

Withdrawal of the rejection is respectfully requested.

CONCLUSION

Applicant respectfully submits that all pending claims (claims 1-9) are in condition for allowance.

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Respectfully submitted,

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